BrainLAB MAR 2 6 2002 K004022

510 (k) Summary of Safety and Effectiveness for m3-micro-Multileaf Collimator

Manufacturer:

Adress: BrainLAB AG
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Contact Person: Mr. Stefan Vilsmeier

Summary Date: December 18, 2000

Device Name:

Trade name: **m3 (micro-Multileaf Collimator)**

Common/Classification Name: Therapeutic X-Ray Collimator

Predicate Device:

m3 (micro-Multileaf Collimator)
Device Classification Name: Therapeutic X-ray Collimator
Regulatory Class: Class II

Intended Use:

The m3 is intended to assist the radiation oncologist in the delivery of radiation to well-defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. In this application, the m3 performs the same function as customized shadow blocks or stereotactic collimators wich have been used for many years. With the arc therapy features, the m3 has the effect of treating patients with a large number of customized shadow blocks, one for each small increment of gantry rotation without the time consuming need to hold irradiation and change shadow blocks in the treatment room at every one or two degrees of rotation.
The m3 is also suitable for IMRT (Intensity Modulated Radiotherapy) treatments.

Device Description:

The m3 is an X-ray Collimator. It comprises multiple motorised tungsten leafs, wich are suited to shaping specific therapeutic X-ray fields, both in a static fashion as well as dynamically via leaf-movement during treatment.
The safety and effectiveness of the m3 System have been demonstrated by the corresponding verification and validation procedures and the m3 system can be used within its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2002

Mr. Stephan Fröhlich
Division Director Radiotherapy
BrainLab AG
Ammerthalstrasse 8
85551 Heimstetten
GERMANY

Re: K004022
Trade/Device Name: m3 (Micro-Multileaf Collimator)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: January 10, 2002
Received: January 14, 2002

Dear Mr. Fröhlich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

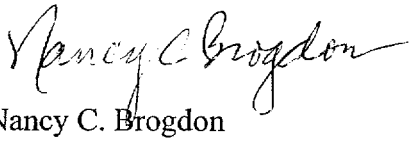
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K004022

Device Name: m3 (micro-Multileaf Collimator)

Indications For Use:

The m3 is intended to assist the radiation oncologist in the delivery of radiation to well-defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. In conjunction with Elekta, Siemens, GE Linacs, the m3 performs the same function as customized shadow blocks or stereotactic collimators. This configuration is suitable for static conformal treatments and "step and shoot IMRT". In addition the advanced integration feature available for Varian Linacs allows to perform "dynamic arc" and "dynamic IMRT" treatments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format I-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K004022